Month xx, 2024

***(Choose either CDER or CBER address below and delete the other)***

U.S. Food and Drug Administration

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*OR*

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WO71, G112

Silver Spring, MD 20993-0002

[CBERDCC\_eMailSub@fda.hhs.gov](mailto:CBERDCC_eMailSub@fda.hhs.gov)

**Subject: IND xxxxxx – Individual Patient IND Annual Report**

**Individual Patient Expanded Access under 21 CFR 312.310**

Dear Division Director / Regulatory Project Manager

In compliance with 21 CFR 312.33, I am submitting an annual report to an Individual Patient Expanded Access IND (please provide IND number) for xxINVESTIGATIONAL DRUGxx submitted on (provide date the IND was submitted to FDA).

This annual report covers the time period from (for the first annual report, state the date you were permitted by FDA to administer treatment) to (the ending date of current summary of treatment).

This document and the included attachments contain the information required by the FDA for submission of an IND Annual Report for the Individual Patient IND xxxxxx which became effective on xx/xx/xxxx for subject (xxINITIALSxx)

1. **Sponsor Name, contact information and list of all authorized contacts**

**Regulatory Sponsor**

Dr. xxNAMExx, MD

Division of \_\_\_\_\_\_\_\_\_\_

Children’s Hospital of Philadelphia (CHOP)

3401 Civic Center Blvd

Philadelphia, PA 19104

Phone:

Email: @chop.edu

**Additional Authorized Contact**

Ms, /Mr, xxNAMEx

Division of \_\_\_\_\_\_\_\_\_\_\_\_

Children’s Hospital of Philadelphia (CHOP)

3401 Civic Center Blvd

Philadelphia, PA 19104

Phone:

Email: @chop.edu

As an additional authorized contact, I request that this individual be copied on email communication from the FDA. Furthermore, this individual is authorized to interact with the FDA on behalf of the sponsor and is permitted to submit and receive regulatory communications.

1. **Brief summary of patient diagnosis, history and current status**

**History:**

* 1. Patient’s initials:
  2. Patient’s gender:
  3. Patient’s current age:
  4. Patient’s last recorded weight:
  5. Patient’s diagnosis (indication for treatment):

xxINITIALSxx is a xx month (or years) old with a history of

*Provide an overall clinical summary and interval history since last annual report or initial submission tothe FDA.*

1. **Treatment Provided**

*Provide summary of treatments since last communication with FDA.*

1. **Plan for Coming Year**

*Provide summary of plan for future treatments or monitoring for this patient for the next year.*

*Examples below:*

*Status of Investigational Product (for example one of the following may apply; ongoing use of product,, manufacturing is progressing to Phase 3 trials, Expanded Access Use Only, company EAP, discontinuing development)*

*Continue with treatment,*

*Monitoring only*

*Move patient to long term follow-up protocol*

1. **IRB Oversight and Communications**

**Initial Review**

Initial IRB Approval for this Individual Patient IND treatment was received on xx/xx/xxxx.

The IRB letter and stamped approved consent are included with this submission.

**Continuing Review**

Continuing IRB Approval for this Individual Patient IND treatment was received on xx/xx/xxxx.

**Amendments**

*List Amendments submitted to the IRB and note if and when these have been submitted to the FDA.*

**Reportable Events**

*List Reportable Events submitted to the IRB and note if and when these have been submitted to the FDA. If no events have occurred state this.*

*Examples of language:*

The Reportable Events are as follows….Or

We have had no Reportable Events since initial approval.

1. **Additional Information**

The following Attachments are included in this submission

* Form 3926
* *CHOP IRB CR concurrence letter and stamped ICF*
* *CHOP IRB amendment letter*
* *IB Edition xx*

Thank you for the ongoing review and incorporation of this information for the Annual Report of IND xxxxxx, for the treatment of this individual patient.

If there are any questions related to this report or anything else related to this IND, please contact me by phone at xxx-xxx-xxxx or email [xxxx@chop.edu](mailto:xxxx@chop.edu). Finally, I authorize xxNAMExx, at phone (xxx-xxx-xxxx) or email [xxxx@chop.edu](mailto:xxxx@chop.edu), to communicate with the FDA on my behalf on all matters related to this particular IND and would request they be copied on any and all email communications.

Sincerely,

xxNAMExx, M.D.,.

Division of xxDIVISIONxx

Children’s Hospital of Philadelphia

Copy to: IND/IDE Support Office

*References – Delete prior to finalizing actual report*

*For Physicians: How to Request Single Patient Expanded Access (“Compassionate Use”)*

[*https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use*](https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use)

*Regulatory Submissions in Electronic and Paper Format for CBER-Regulated Products*

[*https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper-format-cber-regulated-products*](https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper-format-cber-regulated-products)

*Best Practices for Communication Between IND Sponsors and FDA During Drug Development*

[*https://www.fda.gov/files/drugs/published/Best-Practices-for-Communication-Between-IND-Sponsors-and-FDA-During-Drug-Development.pdf*](https://www.fda.gov/files/drugs/published/Best-Practices-for-Communication-Between-IND-Sponsors-and-FDA-During-Drug-Development.pdf)